

## Message Text

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ORIGIN HEW-06

INFO OCT-01 ARA-10 ISO-00 OES-05 RSC-01 /023 R

66607

DRAFTED BY: DHEW/FDA/KJRWEINROTH, MD

APPROVED BY: OES/SCI/BMP:MBEAUBIEN

DHEW/OIH:MACODDING

ARA/BC/C:AISAACS (INFO)/

----- 034406

R 292203Z NOV 74

FM SECSTATE WASHDC

TO AMEMBASSY SANTIAGO

UNCLAS STATE 263352

E.O. 11652: N/A

TAGS: ETRD, EIND, TBIO, CI

SUBJECT: DRUG RECALL - LABEL MIXUP, PRINTING ERROR.

1. FDA ADVISES THAT A PACKAGING ERROR BY WINTHROP'S PRINTER RESULTED IN AN UNDETERMINED QUANTITY OF ISUPREL 1:100, SHELF CASES BEING INCLUDED IN A SHIPMENT OF APPROXIMATELY 27,475 ISUPREL 1:200 SHELF CASES. THE PRODUCT IS AN RX SOLUTION FOR ORAL INHALATION IN 10 ML. GLASS BOTTLES LABELED IN PART: N.D.C. 24-J71-1 ISUPREL HYDROCHLORIDE BRAND OF ISOPROTERENOL HCL, USP SOLUTION 0.5 PERCENT (1:200) FOR ORAL INHALATION ONLY--- USUAL DOSE: 5 INHALATIONS---CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION---WARNING: DO NOT EXCEED THE DOSE PRESCRIBED BY YOUR PHYSICIAN---WINTHROP LABROTORIES, DIVISION OF STERLING DRUG INC., NEW YORK, NY 10016. BOTTLES AND PRODUCT INSERT ARE PLACED IN WHITE CARDBOARD DISPENSING CARTON WHICH READS: PHARMACIST: DISPENSE IN THIS CARTON. DO NOT REMOVE OR COVER THE FOLLOWING: DO NOT USE THE SOLUTION IF IT IS BROWN OR CONTAINS A PRECIPITATE. WARNING: DO NOT EXCEED THE DOSE PRESCRIBED BY YOUR PHYSICIAN. IF DIFFICULTY IN BREATHING PERSISTS, CONTACT YOUR PHYSICIAN IMMEDIATELY. THE WHITE DISPENSING CARTON IS THEN PLACED IN A CARDBOARD LABELING SLEEVE WHICH BEARS THE SAME INFORMATION AS THE BOTTLE LABEL QUOTED ABOVE. TWELVE BOTTLES (IN THE UNIT CARTONS)

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ARE THEN PACKED IN A "SHELF CASE" WHICH IS LABELED TO IDENTIFY

THE PRODUCT ONLY AS FOLLOWS: N.D.C. 24-J71-1 TWELVE BOTTLES, 10 ML. EACH ISUPREL HYDROCHLORIDE BRAND OF ISOPROTERENOL HYDROCHLORIDE, USP 1:200 SOLUTION, WINTHROP LABORATORIES DIVISION OF STERLING DRUG INC., NEW YORK, NY 10016. THE PRINTING IS IN BLACK INK ON UNCOLORED CARDBOARD.

2. THE FOLLOWING LOT NUMBERS ARE INVOLVED: S156LD, S159LD, S182LD, 5064LH, S157LJ, S187LJ. DISTRIBUTION OF THESE LOT NUMBERS COMMENCED ON MAY 20, 1974 AND CONTINUED THROUGH EARLY NOVEMBER. IT IS ESTIMATED 6,000 SHELF CASES REMAIN ON THE MARKET. FOREIGN CONSIGNEE AS FOLLOWS:

SYDNEY ROOS CO., (LTDA), CASILLA 163-D, SANTIAGO DE CHILE, CHILE - 833 SHELF CASES OF LOT NO. S187LJ.

3. POST IS REQUESTED TO DETERMINE IF FOREIGN CONSIGNEE IS FAMILIAR WITH DETAILS OF RECALL AND TO NOTIFY CONSIGNEE THAT STOCKS BE EXAMINED AND ANY MISLABELED SHELF CASES FOUND SHOULD BE DESTROYED AND WINTHROP BE NOTIFIED OF THEIR ACTION. INGERSOLL

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** LABELING, DRUGS, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 29 NOV 1974  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1974STATE263352  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** DHEW/FDA/KJRWEINROTH, MD  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Film Number:** D740347-0798  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
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**Legacy Key:** link1974/newtext/t1974112/aaaaabeg.tel  
**Line Count:** 81  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 2  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Review Action:** RELEASED, APPROVED  
**Review Authority:** golinofr  
**Review Comment:** n/a  
**Review Content Flags:**  
**Review Date:** 12 NOV 2002  
**Review Event:**  
**Review Exemptions:** n/a  
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30 JUN 2005

**Review Media Identifier:**  
**Review Referrals:** n/a  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** DRUG RECALL - LABEL MIXUP, PRINTING ERROR.  
**TAGS:** ETRD, EIND, TBIO, US, FDA, WINTHROP  
**To:** SANTIAGO  
**Type:** TE  
**Markings:** Declassified/Released US Department of State EO Systematic Review 30 JUN 2005